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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,299	01/17/2002	Michael A. Zasloff	MZ 100	5008

7590 04/06/2007  
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EXAMINER
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SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/053,299

Applicant(s)

ZASLOFF ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-9 and 43-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-9 and 43-50 is/are allowed.
- 6) ☒ Claim(s) 51-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **Status of the Application**

Receipt of Applicant's Amendment and Arguments after BPAI decision filed 03/14/07 is acknowledged.

Claims 1, 3-9 and 43-53 are pending in this action. Claims 1, 3, 4 and 6 have been amended. New claims 43-53 have been added. Claims 2 and 10-42 have been cancelled. Claims 1, 3-9 and 43-50 are allowed. Claims 51-53 are rejected.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an effective microbial blocking quantity to be from "0.1 ug/cm<sup>2</sup> to 1 gm/cm<sup>2</sup>, (see specification page 2, lines 16-19), does not reasonably provide enablement for a microbial blocking quantity of "at least about 0.1 ug/cm<sup>2</sup> as instantly claimed (see claim 51). The limitation of "0.1 ug/cm<sup>2</sup>" only occurs within a range and there is no showing that amounts above this range is effective. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added claim limitation "at least about 0.1 ug/cm<sup>2</sup>" introduces new matter into the claims. The limitation "at least about 0.1 ug/cm<sup>2</sup>" occurs only within a range, and not outside of a range (see specification page 2, lines 16-19).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng (U.S. Patent No. 6,770,306).**

**Zeng ('306)** teaches a pharmaceutical composition comprising amino acids, oligopeptides and/or polypeptides, which can change the metabolic process of bacteria in the vagina and reduce vaginal acid production (col. 3, lines 45-47). The compositions can be used to treat high acidity vaginitis and fungal vaginitis (col. 6, lines 35-40). In one example, Zeng applied a mixture of amino acids, including isoleucine, to a female patient diagnosed with 'high acidity in vagina accompanying fungal infection' (col. 13, Experimental Example 4; columns 8-9, Example 8). After application of the drug for three days, there was no evidence of fungal spores.

With regards to the area of drug delivery and for the reasons stated by the Board, the Examiner has adopted the BPAI's position regarding the locality of administration. At column 4, lines 47-49 of Zeng, it is stated that "the composition containing only one or two sodium salts of amino acids can also partly realize the object of the invention. This statement constitutes a description of a composition of one amino acid that is able to partly achieve Zeng's goal of treating vaginitis. Applicant claims delivery to an epithelial cell surface, such as the urinary tract. The compositions disclosed by Zeng are formulated for use in the urinary tract, namely for use in the vagina and thus meets the claim limitations. Burden is shifted to Applicant to establish that the delivery would not be targeted for epithelial surfaces, such as the urinary tract, and more specifically, to areas for targeting vaginitis.

Zeng teaches that the total content of amino acids in a composition is preferably 30-350 mmol/L (col. 5, lines 3-4). When isoleucine is the only amino acid in the composition, it would

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be present in an amount of 0.393%, which falls within the ranges described (specification p. 18, line 13) and claims 11-13. Accordingly, because Zeng's concentration of isoleucine falls within the disclosed and claimed effective concentrations, it is reasonable to have presumed that Zeng's composition would block microbial adherence.

Moreover, it is deemed *prima facie* obvious to one of ordinary skill in the art to determine suitable or effective concentrations using routine or manipulative experimentation to obtain the best possible results, as these are variable parameters obtainable within the art.

#### ***Allowable Subject Matter***

Claims 1, 3-9 and 43-50 are allowed.

#### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



HUMERA N SHEIKH  
PRIMARY EXAMINER

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April 02, 2007

*hns*